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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,378	08/26/2003	Alan M. Fogelman	407T-911270US	4598

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EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 11/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/649,378	FOGELMAN ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-191* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-191* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-93, and claims 123-191 (as they depend from claims 1-93), drawn to tripeptides and tetrapeptides, compositions and kits comprising the same, and therapeutic methods of using the same, classified in class 514, subclass 18.

II. Claims 94-111, and claims 123-191 (as they depend from claims 94-111), drawn to pentapeptides, compositions and kits comprising the same, and therapeutic methods of using the same, classified in class 514, subclass 17.

III. Claim 112, and claims 123-191 (as they depend from claim 112), drawn to peptides having from 5 to 11 amino acids with acidic and basic non-terminal amino acids, compositions and kits comprising the same, and therapeutic methods of using the same, classified in class 514, subclass 15-17.

IV. Claim 113, and claims 123-191 (as they depend from claim 113), drawn to peptides having from 5 to 11 amino acids with acidic or basic non-terminal amino acids and with aliphatic non-terminal amino acids, compositions and kits comprising the same, and therapeutic methods of using the same, classified in class 514, subclass 15-17.

V. Claim 114, drawn to peptides having from 5 to 11 amino acids with acidic or basic non-terminal amino acids and with aromatic non-terminal amino acids, compositions and kits comprising the same, and therapeutic methods of using the same, classified in class 514, subclass 15-17.

VI. Claim 115, and claims 123-191 (as they depend from claim 115), drawn to peptides having from 6 to 11 amino acids with aromatic non-terminal amino

acids, compositions and kits comprising the same, and therapeutic methods of using the same, classified in class 514, subclass 15-17.

VII. Claims 116-118, and claims 123-191 (as they depend from claims 116-118), drawn to peptides having from about 10 to about 30 amino acids, comprising at least class A amphipathic helix, and one or more aliphatic or aromatic amino acids at the center of the non-polar face of the amphipathic helix, compositions and kits comprising the same, and therapeutic methods of using the same, classified in class 514, subclass 12-15.

VIII. Claims 119-122, and claims 123-191 (as they depend from claims 119-122), drawn to peptides having from about 10 to about 30 amino acids, comprising at least class A amphipathic helix, and covalently coupled to a biotin, compositions and kits comprising the same, and therapeutic methods of using the same, classified in class 514, subclass 12-15.

The inventions are distinct, each from the other because:

The invention of Groups I-VIII concern patentably distinct peptides. Tri-, tetra-, and penta-peptides are patentably distinct from peptides having from 6 to about 30 amino acids because of their materially different numbers of amino acids. The peptides of Groups II-VIII have materially amino acid sequences from one another. For peptides having relatively few amino acids, differences in number and/or identity of the amino acids are material because of the relatively large effect that any single amino acid will have on the peptide's conformation and activity.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-VIII, and the search required for Group II is not required for Groups I, VII, or VIII, restriction for examination purposes as indicated is proper.

2. (a) If Applicants elect the invention of Group I, the following election of species requirements are additionally imposed:

This application contains claims directed to the following patentably distinct species of the claimed invention: Claims 2-26, claims 27-49, claims 50-71, and claims 72-93 are drawn to patentably distinct peptides having materially different numbers of amino acids and/or amino acid sequences. Claims 131-191 are drawn to patentably distinct methods of treating atherosclerosis, rheumatoid arthritis, lupus erythematous, polyarteritis nodosa, osteoporosis, Altzheimer's disease, multiple sclerosis, and viral illnesses. These methods are materially different from one another because of their materially different causes and symptoms. (The methods drawn to enhancing the activity of a statin are grouped with the methods for treating atherosclerosis.)

Applicant is required under 35 U.S.C. 121 to elect a single group of peptides and a single method of treatment for prosecution on the merits to which the claims shall be restricted if no

generic claim is finally held to be allowable. Currently, claims 1, 123-130, 141-150, and 175-186 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

(b) If Applicants elect the invention of Group I, the following sequence restriction requirement is additionally imposed:

Claims 14, 39, 60, 61, 82, and 83 are generic to a plurality of disclosed patentably distinct sequences comprising: SEQ ID NOS:109-432. These sequences are patentably distinct, each from the other, because of their materially different amino acid sequences. Searching all of the claimed sequences would constitute an undue burden on the examiner because different sequence

searches would be required for each of the claimed sequences. Applicant is required under 35 U.S.C. 121 to elect a single disclosed sequence, even though this requirement is traversed.

Should applicant traverse on the ground that the sequences are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the sequences to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This is not a species election, but a holding that the sequences are patentably distinct, one from the other.

3. If Applicants elect the invention of Group II, the following sequence restriction is additionally imposed:

Claims 104 and 105 are generic to a plurality of disclosed patentably distinct sequences comprising: SEQ ID NOS:433-447. These sequences are patentably distinct, each from the other, because of their materially different amino acid sequences. Searching all of the claimed sequences would constitute an undue burden on the examiner because different sequence searches would be required for each of the claimed sequences. Applicant is required under 35 U.S.C. 121 to elect a single disclosed sequence, even though this requirement is traversed.

Should applicant traverse on the ground that the sequences are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the sequences to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This is not a species election, but a holding that the sequences are patentably distinct, one from the other.

4. If Applicants elect the invention of Group VII, the following sequence restriction is additionally imposed:

Claims 117 and 118 are generic to a plurality of disclosed patentably distinct sequences comprising: SEQ ID NOS:107-108. These sequences are patentably distinct, each from the other, because of their materially different amino acid sequences. Searching all of the claimed sequences would constitute an undue burden on the examiner because different sequence searches would be required for each of the claimed sequences. Applicant is required under 35 U.S.C. 121 to elect a single disclosed sequence, even though this requirement is traversed.

Should applicant traverse on the ground that the sequences are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the sequences to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This is not a species election, but a holding that the sequences are patentably distinct, one from the other.

5. If Applicants elect the invention of Group VIII, the following sequence restriction is additionally imposed:

Claims 121 and 122 are generic to a plurality of disclosed patentably distinct sequences comprising: SEQ ID NOS:451-465. These sequences are patentably distinct, each from the other, because of their materially different amino acid sequences. Searching all of the claimed

sequences would constitute an undue burden on the examiner because different sequence searches would be required for each of the claimed sequences. Applicant is required under 35 U.S.C. 121 to elect a single disclosed sequence, even though this requirement is traversed.

Should applicant traverse on the ground that the sequences are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the sequences to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This is not a species election, but a holding that the sequences are patentably distinct, one from the other.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

November 5, 2004